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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,430	04/08/2004	Charli Kruse	B1180/20026	7174
3000 7590 06/09/2010 CAESAR, RIVISE, BERNSTEIN, COHEN & POKOTILOW, LTD. 11TH FLOOR, SEVEN PENN CENTER 1635 MARKET STREET PHILADELPHIA, PA 19103-2212				
			EXAMINER	
			HAMA, JOANNE	
			ART UNIT	PAPER NUMBER
			1632	
			NOTIFICATION DATE	DELIVERY MODE
			06/09/2010	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@crbcp.com

### Office Action Summary

**Application No.**

10/820,430

**Applicant(s)**

KRUSE, CHARLI

**Examiner**

JOANNE HAMA

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 March 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 3, 5-7, 9-14, 48-65 and 67-86 is/are pending in the application.
- 4a) Of the above claim(s) 14, 48-50 and 72-75 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3, 5-7, 9-13, 51-65, 67-71, 76-86 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

Applicant filed a response to the Non-Final Action of September 3, 2009 on March 9, 2010 and December 3, 2009. It is noted that the response on March 9, 2010 addresses a non-compliant amendment.

Claims 1, 2, 4, 8, 15-47, 66 are cancelled. Claims 3, 62, 76 are amended. Claims 14, 48-50, 72-75 are withdrawn.

Per the species election of September 25, 2006, Applicant has elected pancreas (and acinar tissue of pancreas) as the species to be examined.

Claims 3, 5-7, 9-13, 51-65, 67-71, 76-86, drawn to a composition consisting of isolated pluripotent adult stem cells obtained from acinar tissue of the pancreas, are under consideration.

**Withdrawn Rejection****35 USC § 102**

Applicant's arguments, see pages 7-8 of Applicant's response, filed December 3, 2009, with respect to the rejection of claims 3, 5-7, 9-13, 51-56, 59, 62-65, 67-71, 76-81, 84 as being anticipated by Clarke et al., 2000, Science, 288: 1660-1663 have been fully considered and are persuasive. Applicant indicates that the cells isolated by Clarke et al. depend on activation or induction in a suitable environment (Clarke et al., page 1660 and page 1661) and do not disclose any spontaneous differentiation of the stem cells. The rejection of claims 3, 5-13, 51-56, 59, 62-71, 76-81, 84 has been withdrawn. The rejection of claims 8, 66 is withdrawn as the claims are cancelled.

**Maintained Rejection**

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 5-7,9-13, 51-65, 67-71, 76-86 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Zulewski et al., 2001, Diabetes, 50: 521-533, see IDS, Apte et al., 1998, Gut, 43: 128-133, see IDS, Pittenger et al., 1999, Science, 284: 143-147, for reasons of record, September 3, 2009.

Applicant's arguments filed December 3, 2009 have been fully considered but they are not persuasive.

Applicant indicates that the Examiner asserts that the presence of "nestin-positive cells" appears to be used as a synonym for "pluripotent cells." However, Zulewski describes nestin as a neural cell specific stem cell marker (see abstract of Zulewski reference) and the isolated cells are merely multipotent and are capable of differentiating into pancreatic endocrine, exocrine, and hepatic phenotypes. As such, at the date of the present invention, the skilled artisan did not get any hint from Zuleswki et al., who describe nestin-positive cells and merely multipotent cells, that true pluripotent cells may be obtained from the pancreas (Applicant's response, page 10). In response, this is not persuasive.

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Regardless of what Zuleswki et al. thought that their cells' developmental potential was based their expression of nestin, an artisan would have isolated and made clones of the cells from Zuleswki et al. because at least they can be used to obtain pancreatic and hepatic cells. While Zuleswki et al. do not specifically teach that their cells had potential to become other types of differentiated cells, as far as can be told, the Zuleswki et al.'s cells have the ability to differentiate into cell types other than pancreatic and hepatic because Zuleswki et al.'s cells were obtained the same way as described in the specification.

Applicant indicates that Pittenger et al. teach cultivation of mesenchymal stem cells and their capability to differentiate into several cell types. Apte et al. do not teach the isolation of pluripotent or multipotent cells (Applicant's response, page 11). In response, Pittenger et al. and Apte et al. were cited to show how to obtain cells from the acini of pancreas (Apte et al.) and how to obtain a single cell from a mixture of cells (Pittenger et al.). See Office Action, September 3, 2009, pages 5-6.

Thus, the claims remain rejected.

It is noted that the rejection of claims 8, 66 is withdrawn as the claims are cancelled.

### ***Conclusion***

No claims allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Mondays, Tuesdays, Thursdays, and Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR)

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can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Joanne Hama/  
Primary Examiner  
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